



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 16 2005

The Honorable Tom A. Coburn, M.D.
United States Senate
Washington, D.C. 20510

Dear Senator Coburn:

I am replying to the letter you and Senator Inhofe sent expressing your concerns about the incidence of human papillomavirus (HPV) and cervical cancer and inquiring about the status of efforts by several components of the Department of Health and Human Services that are involved in addressing these diseases. I appreciate the opportunity to address your questions and concerns.

First, with regard to your concern about condom labeling, I am pleased to advise you that a regulation has been submitted to the Office of Management and Budget for review and we look forward to issuing this rule for public comment in the near future.

Second, with regard to your concern about the Centers for Disease Control and Prevention's (CDC) HPV related activities referenced in PL 106-554, I asked Dr. Gerberding, the Director of the CDC, to provide me with an up-to-date status report of their activities, and I am enclosing the document.

With regard to your concern about a study on HPV supported by the National Institutes of Health (NIH) and under the direction of the H. Lee Moffitt Cancer Center & Research Institute, I am taking this matter seriously and am referring it to our Office of Human Research Protection for immediate review and action.

Thank you for your warm wishes on the occasion of my confirmation as Secretary, and for taking the time to write to me about this important public health issue. I look forward to working with you throughout my term toward bettering the health and well-being of all Americans. Senator Inhofe will receive a separate letter.

Sincerely,

Michael O. Leavitt

Enclosure

Since the passage of Public Law 106-554 in December 2000, CDC has undertaken a number of activities to respond to the requirements of the law in three main areas: surveillance, research, development and dissemination of educational materials. Surveillance activities include sentinel surveillance of HPV prevalence over time and a national, population-based survey (NHANES) to determine the presence of HPV DNA in women and seroprevalence of HPV-16 antibody in men and women. Research activities include a two-phased behavioral research study to determine the impact of an HPV-related diagnosis on women; formative research to inform CDC on the development of educational messages and information for the public, patients, and their partners; and a national survey of health-care providers to assess knowledge, attitudes, and practices related to HPV infection.

To comply with provisions in the law to educate the public about HPV, CDC developed an HPV website that contains information targeted to the general public, including an HPV fact sheet available in both English and Spanish and weblinks to scientifically accurate HPV information on other credible websites. These resources provide information about a range of topics including modes of transmission, consequences of infection (especially cervical cancer), the importance of regular Pap smears for prevention of cervical cancer, and medically accurate information about the effectiveness of condoms in preventing HPV infection. The website (<http://www.cdc.gov/std/HPV/default.htm>) went live in December 2004 and has received almost 100,000 visits. To supplement the website information for the general public, CDC is in the final stages of developing additional HPV educational print materials which will be appropriate for a low-literacy audience and available in five languages.

To inform the development of the additional educational materials, CDC contracted with Ogilvy Public Relations Worldwide to conduct qualitative research on messages and tone for HPV educational materials directed to the general public. The qualitative research included 14 focus groups in five cities with both sites and focus group participants selected based on national cervical cancer incidence data and demographics. Details about the cities and focus group participants and a copy of the focus group discussion guide are in the section on Focus Group Activity). A second round of 15 focus groups is being conducted in February 2005 to test specific prototype materials. Educational materials will be completed in April 2005.

The CDC has held one consultation meeting related to activities conducted in response to Public Law 106-554 (January 19, 2005) to inform CDC in the development of educational materials. The purpose of the meeting was to obtain reaction to the preliminary results of the first 14 focus groups (see Focus Group Activity). Representatives of a variety of organizations interested in and knowledgeable about women's health and HPV provided reactions and suggestions that have informed the second round of focus groups in which the prototype materials are currently being tested. We have included a list of the participating organizations in the section on Focus Group Activity. If you are interested in learning more about this consultation process, CDC would welcome the opportunity to review any specific details with you or your staff.

Focus Group Activities

The first round of 14 focus groups to test message concept and tone were conducted in the following U.S. cities:

- Detroit, Michigan
- Houston, Texas
- Los Angeles, California
- Louisville, Kentucky
- Washington, DC

Participants in the focus groups were recruited and screened to ensure representation from the following groups of people:

- women ages 18 to 29 years of age who are either sexually active or considering becoming sexually active
- women ages 30 – 45 years of age who are either sexually active or may become sexually active
- women with low socio-economic status;
- women of color
- men ages 18 to 45 years of age who are either sexually active or considering becoming sexually active

CDC Consultation

As part of the project to research and develop educational materials for the general public, CDC held a consultation meeting on January 19, 2005, to obtain reaction to the preliminary results of data from the first round of 14 focus groups on message and tone of HPV messages. Present at the meeting were representatives of the following organizations, a cross-section of organizations interested in women's health and HPV:

- 3M Pharmaceuticals
- American Academy of Pediatrics
- American Cancer Society
- American College Health Association
- American Social Health Association
- Asian and Pacific Islander American Health Forum
- Cytoc Corporation
- Digene Corporation
- GlaxoSmithKline Vaccines
- Medical Institute for Sexual Health
- Merck Vaccines
- National Alliance for Hispanic Health
- National Coalition of STD Directors
- National Council of La Raza
- National Family Planning and Reproductive Health Association
- National Indian Health Women's Resource Center
- Ogilvy Public Relations Worldwide
- Planned Parenthood Federation of America
- TriPath Imaging, Inc

Updated Timeline in CDC's Response to HPV Law

In August 2003, CDC made a progress report to Congress on HPV activities mandated by Public Law 106-554 in which a list of activities undertaken was provided, with estimated timetable for completion. The following is a summary of that list of activities, CDC progress to date, and projects still underway:

Sentinel Surveillance (PL 106-554, Sec. 317P (a))**317(a)(2) Report**

Analysis of HPV prevalence over time and risk factors associated with HPV infection.

Preliminary report was completed in the fall of 2004, with final report expected in the fall of 2006.

Special research studies.

Prevalence of genital HPV DNA in vaginal specimens among a nationally representative sample of 14 – 59 year-old women; seroprevalence of antibody to HPV-16 among a nationally representative sample of 14 – 59 year-old men and women.

Prevention Activities; Education Program (PL 106-554, Sec. 317P (b))**Sec. 317P (b) (1) (A) and (B) Behavioral research (PL 106-554,)**

Multi-site behavioral study of the impact of HPV-related diagnosis.

Phase 1: Results from focus groups and in-depth interviews to determine knowledge, attitudes, behaviors and impact of high risk HPV (HR-HPV) diagnosis on women; and health care providers' perceptions of the informational needs of HR-HPV+ patients.

Interim report with data from two sites was completed in June 2004, and the final report with data from all four sites was completed in December 2004.

Phase 2: Results from a common quantitative instrument administered by all sites. Core elements for the instrument were developed from the qualitative research from Phase 1. First interim report with data from two sites will be completed in March 2005; second interim report with data from two additional sites will be completed in October 2005. Final report with data from all four sites will be completed in March 2006.

Prevention Activities; Education Program (PL 106-554, Sec. 317P (b))**Surveys of physician knowledge (PL 106-554, Sec. 317P (b) (1) (C))**

Survey of physician knowledge, attitudes and practices about genital HPV infection.

Assessment of providers' knowledge, attitudes and practices related to HPV; providers' perceptions of risks and benefits of HPV testing and counseling; perceptions about offering HPV testing and counseling in the future; and determination of barriers to and facilitators of appropriate HPV prevention, testing and counseling practices. Preliminary report was completed December 2004, and the final report will be completed in April 2005. Information from the preliminary report is currently being used to inform the development of educational materials for health care providers and patients.

Prevention Activities; Education Program (PL 106-554, Sec. 317P (b))**Survey of public knowledge (PL 106-554, Sec. 317P (b) (1) (C))**

Survey of the public's knowledge, attitudes and practices about genital HPV infection.

Qualitative assessment of the general public's HPV-related knowledge, attitudes and current practices; preferred communication channels; and credible sources of information. Preliminary report was completed in November 2003, and final report was completed in December 2003.

Qualitative research on messages and tone of HPV information through a series of 14 focus groups in five cities throughout the U.S. among African-American, Hispanic and Caucasian women and men. Based on information from the focus groups, specific messages and materials are being tested with 15 additional focus groups comprised of African Americans, Hispanics, Caucasians, Native Americans and Asian Americans. Preliminary report on the first round of focus groups was completed in January 2005. Testing of messages and materials will be completed in April 2005.

Prevention Activities; Education Program (PL 106-554, Sec. 317P (b))

Educational materials (PL 106-554, Sec. 317P (b) (1) (D))

Educational materials for the public.

Educational materials for the public are being developed based on information from the formative research described above and include information on modes of transmission, consequences if infection, including the link between HPV and cervical cancer; the available scientific evidence on the effectiveness of lack of effectiveness of condoms in preventing infection with HPV; and the importance of regular Pap smears for early intervention and prevention of cervical cancer. An HPV webpage was developed and posted in December 2004. To supplement the information currently on the HPV website, print general public educational materials will be completed in April 2005.

Prevention Activities; Education Program (PL 106-554, Sec. 317P (b))

Report (Prevention Activities; Education Program (PL 106-554, Sec. 317P (b)(2))

Interim report dated August 2003

Final report dated January 2004

HPV Education and Prevention (PL 106-554, Sec. 317P (c))

Educational materials for the public, health care providers and patients.

General public educational materials are being developed in five languages and distributed through a variety of electronic and print channels, based on the findings of the research described above. An HPV webpage was developed and posted in December 2004. General public educational materials, in addition to the information currently on the HPV website, will be completed in April 2005. Based on the data in the provider surveys described above, educational materials for providers and patients will be completed in June 2005. In addition to CDC's on-going efforts to educate providers through development of guidelines, provision of continuing medical education through a network of Prevention Training Centers, CDC-developed HPV curricula, published research, MMWRs and Dear Colleague letters, CDC will produce new HPV materials for health care providers that will include appropriate use of HPV testing and guidance on counseling patients and their partners and will conduct a national webcast to update and educate health care providers. The materials will be completed in June 2005 and the webcast will occur in the fall of 2005.

Summary of CDC HPV Activities Related to Public Law 106-554

Deliverable	Description	Target Completion	Completion	Comments
Surveillance and Special Research (PL 106-554, Sec. 317P (a))				
Sentinel Surveillance	Analysis of HPV prevalence over time and risk factors associated with HPV infection.	Preliminary Fall 2004 Final Fall 2006		
Special Research Studies	Prevalence of genital HPV DNA, in vaginal specimens, among nationally representative sample of 14-59 year old women; seroprevalence of antibody to HPV-16 among a nationally representative sample of 14-59 year old men and women. NHANES	Late 2005/early 2006 for data analysis to be complete		
Prevention Research (PL 106-554, Sec. 317P (b) (1) (A) (B))				
Multi-site behavioral study of Impact of high-risk HPV-related diagnosis (HR-HPV)				
Phase 1	Results from focus groups and in-depth interviews conducted through 2 universities; includes knowledge, attitudes, behaviors and impact of HR-HPV diagnosis on women; health care providers' perceptions of informational needs of HR-HPV+ pts. Population includes African Americans, Hispanics and Caucasians.	Interim Report completed 6/2004	Interim Report completed 6/2004	
	Information on knowledge, attitudes, behaviors and impact of HR-HPV diagnosis on women and their male sexual partners. Data obtained from focus groups and in-depth interviews with African American, Caucasian, Hispanic, Asian and American Indian women, men and adolescents. Information on health care providers' perceptions of informational needs of HR-HPV+ pts from a focus group conducted with health care providers at one of the research sites.	Final Report 12/2004	Final Report completed 12/2004	
Phase 2	Preliminary findings based on data from 3 sites. Data obtained from core elements in a quantitative instrument administered by all sites. Population will include HR-HPV+ and HR-HPV- African American, Caucasian, Hispanic and American Indian women.	Interim Report 3/2005		
	Information from core elements in a quantitative instrument administered by all sites. Core elements for the instrument developed from qualitative research and include: HPV knowledge, counseling received from HCP after HR-HPV diagnosis; often-used, most trusted and preferred sources for HPV educational information; disclosure of HPV diagnosis; sexual history, practices and behaviors; partners' responses to HPV diagnosis; emotional impact of HR-HPV+ and HR-HPV- women. Analysis will compare women by ethnicity, time since diagnosis and HR-HPV status	Second Interim Report 10/2005 with preliminary data from 2 additional sites included. Final all-site report 3/2006.		
Surveys of Physician Knowledge, Attitudes and Practices about Genital HPV Infection (PL 106-554, Sec. 317P (b) (1) (C))				
	Assessment of providers' knowledge, attitudes and practices related to HPV; assessment of providers' perceptions of risks/benefits of HPV testing and counseling; barriers and facilitators to appropriate HPV prevention, testing and counseling practices; assessment of perceptions of offering HPV testing and counseling in the future	Final Report 4/2005 Peer-reviewed papers 9/2005	Preliminary Report completed 12/2004	
Survey of Public Knowledge, Attitudes and Practices about Genital HPV Infection (PL 106-554, Sec. 317P (b) (1) (C) and D, and (e))				
	Summary of focus group results. Information on general public's HPV-related knowledge, attitudes and current practices, as well as information on preferred communication channels, message tone and credible sources of information		Final Report completed 12/2003	
	Develop and disseminate educational materials for patients, partners and general public	12/2004 for general public 6/2005 for patients and partners	HPV website live in 12/2004	Additional print materials for general public in English and Spanish in 4/2005. Materials in other 3 languages will be completed after additional community-building and focus groups.
	Develop and disseminate educational materials for providers	6/2005		